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Dkt. 50659/JPW/AJM/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	David Baltimore et al.	
Serial No.	:	08/813,323 (CPA)	Examiner: Minh-Tam Davis
Filed	:	March 10, 1997	Group Art Unit: 1642
For	:	TRUNCATED CRAF1 INHIBITS CD40 SIGNALING	

1185 Avenue of the Americas
New York, New York 10036
November 21, 2001

Dec. 5, 01

Honorable Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

COMMUNICATION IN RESPONSE TO MAY 23, 2001 OFFICE ACTION AND PETITION FOR THREE-MONTH EXTENSION OF TIME

This Communication is submitted in response to a May 23, 2001 Office Action issued in connection with the above-identified application. A response to the May 23, 2001 Office Action was due August 23, 2001. Applicants hereby petition for a three-month extension of time in which to respond to the May 23, 2001 Office Action. The fee for a three-month extension of time for a small entity is FOUR HUNDRED AND SIXTY DOLLARS ($460.00), and a check for this amount is enclosed. Small entity status has been previously established and is still valid. With a three-month extension of time, a response is due November 23, 2001. Accordingly this Communication is being timely filed.

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Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected Claims 3, 4, and 92 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner stated that Claims 3, 4, and 92 are drawn to a protein which comprises an amino acid sequence which a) is included in SEQ ID NO:1, b) has at its carboxy terminus a proline as shown at position number 567 of SEQ ID NO:1, c) comprises continuous amino acids as shown in SEQ ID NO:1 between the proline at position 567 and the serine at position number 385, and d) does not extend at its amino terminus beyond the serine shown in SEQ ID NO:1 at position number 324.

The Examiner also stated that the specification discloses a protein comprising CRAF1 truncated by from about 323 to about 414 amino acid residues at the amino terminus.

The Examiner asserted however, that although the specification discloses truncation spanning from about amino acid 323 to amino acid 414, the specification neither discloses nor contemplates truncation at amino acid residue number 385.

In response, applicants respectfully traverse the Examiner's rejection.

Page 8, lines 3-5 of the specification, as originally filed,

discloses a protein comprising a portion of CRAF1. This portion has as its carboxy-terminal boundary residue number 567 of SEQ ID NO:1. The portion has as its amino-terminal boundary any one of amino acid residues from 324 to 415 of SEQ ID NO:1. It is important to note that the portion of CRAF1 disclosed in the specification has an amino terminus which can only be one of 92 defined amino acid residues. Given that applicants were in possession of the CRAF1 amino acid sequence at the time of filing, it is clear that they were in possession of 92 distinct CRAF1 portions, each portion having an amino terminus at one of these 92 possible positions. One of these 92 possible positions is position 385 occupied by serine. Thus at the time of filing, applicants were clearly in possession of a CRAF1 portion whose amino terminus is residue 385 as shown in SEQ ID NO:1. No further language in the specification is necessary to establish applicants' possession of this particular CRAF1 portion. That is, no explicit recitation of a CRAF1 portion having a terminus at position 385 is warranted in order to demonstrate applicants' possession of such portion. For the same reasons, one of skill in the art reading the specification would also be in possession of this CRAF1 portion.

The Examiner also rejected claims 3, 4, and 92 as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3, 4 and 92 are discussed above. The Examiner stated that the claimed variants consist of substitutions wherein valine is substituted for glycine or vice versa.

The Examiner stated that the specification discloses that conservative substitutions include the substitution of one amino acid for another with similar characteristics, such as substitution of valine for glycine (p. 8, second paragraph). The Examiner also stated that there is no disclosure whether there is retention of the activity of the claimed variant proteins. The Examiner further stated that although conservative substitutions increase the chance of having less effect on the activity of the protein, it is unpredictable which amino acid at a certain position could be substituted even by conservative substitution. For example, the Examiner stated that Straub P et al, 1993, J Biol Chem 268(29):21997-23003, teach that conservative substitutions of valine for glycine at positions 111 and 117 of cytochrome P450 2C2 result in about 50- and 7-fold reduction of activity, respectively. The Examiner also stated that Kouklis PD et al, 1993 J Cell Science, 106(pt 3): 919-28, teach that a single exchange of glycine 450 of the intermediate filament protein vimentin with valine strongly interferes with the normal assembly of the intermediate filaments. The Examiner asserted that in view of the above, it would require undue experimentation for one of skill in the art to practice the claimed invention.

In response, applicants respectfully traverse the Examiner's rejection.

The cited publications merely state that the activity of certain proteins are altered by conservative substitutions, including reduction of activity.

However, each of these publications relates to altered protein

activity in only one out of the virtually infinite number of known proteins. Indeed the Examiner has failed to demonstrate through citation or otherwise that conservative amino acid changes are more likely than not to significantly impair the protein's function. Additionally, applicants note that the claims are directed to variants having at least some activity. The Examiner's presumption that all such variants must have the same or greater activity than those exemplified in the specification is not justified. In summary, the Examiner has failed to show why the claimed variants should be presumed inoperable absent explanation.

In view of the above remarks, applicants maintain that claims 3, 4, and 92 satisfy the enablement requirement of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 3, 4, and 92 under 35 U.S.C. §102(b) as allegedly anticipated by Sato, et al.

Claims 3, 4, and 92 are discussed above.

The Examiner asserted that the protein comprising residues 363-543 taught by Sato, et al. meets all the limitations of the claims.

In response, applicants respectfully traverse the Examiner's rejection.

For a protein to fall within the scope of the rejected claims, it must have both a carboxy-terminus at residue 567 of SEQ ID NO:1 and

an amino-terminus between residues 324 and 385 of SEQ ID NO:1. The protein of Sato fails to fall within the scope of these claims. Specifically, that protein's amino-terminus occurs at residue 387 of SEQ ID NO:1 - and not between residues 324 and 385 as required. Accordingly, Sato, et al. fail to anticipate the rejected claims.

In view of the above remarks, applicants maintain that claims 3, 4, and 92 satisfy the requirements of 35 U.S.C. §102(b).

In summary, in light of the remarks made hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of rejection set forth in the May 23, 2001 Office Action.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed fee of FOUR HUNDRED AND SIXTY DOLLARS ($460) for a three-month extension of time, is deemed necessary in connection with the filing of this Communication. If any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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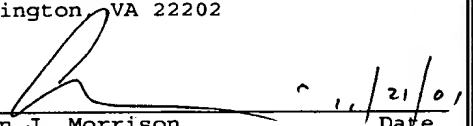
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Honorable Commissioner for Patents, P.O. Box 2327 Arlington, VA 22202



11/21/01

Alan J. Morrison Date
Reg. No. 37,399